



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,026	08/22/2000	Lytton A. Williams	22167-703	1293

21971 7590 03/25/2002

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 943041050

EXAMINER

PRIDDY, MICHAEL B

ART UNIT	PAPER NUMBER
----------	--------------

3732

DATE MAILED: 03/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/644,026

Applicant(s)
Williams et al.

Examiner
Michael Priddy

Art Unit
3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 14, 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-65 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/are allowed.
- 6) ☒ Claim(s) 41, 43-51, 53, 55-62, 64, and 65 is/are rejected.
- 7) ☒ Claim(s) 42, 54, and 63 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20) ☐ Other: _____

Art Unit: 3732

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 55 recites the limitation "a lumen at least .5 mm in diameter" while claim 53 has already provided for "a lumen extending longitudinally within the anchoring elements". It is therefor unclear whether the language of claim 55 is intended to refer to an additional lumen or that/those recited in claim 53.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 41, 44-51, 53, 56-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable Büttner-Janz et al. (5,401,269) over in view of Steffee (5,071,437). Büttner-Janz

Art Unit: 3732

et al. teach an intervertebral disc endoprosthesis comprising a bottom plate 1, a top plate 2, and a prosthesis core 3 having convex superior and inferior surfaces which articulate with concave inner surfaces of the plates 1 and 2. The exterior surfaces of plates 1 and 2 include beveled, projecting teeth 5 for penetrating into the endplates of the vertebrae. Therefor, Büttner-Janz et al. teach all of the limitations of the present invention except that the teeth 5 comprise lumens extending therewithin. Concerning the limitations of claim 50, requiring the intradiscal component be coupled to either the first or second anchor plates, the examiner directs applicants attention to Figs. 8 and 9 in which core 3 includes a rib 11 and each of the plates 1 and 2 include grooves for receipt of the rib 11. This couples the core 3 to each of the plates 1 and 2.

Steffee teaches an artificial disc 5 which comprises an upper flat plate 12, a lower flat plate 14 and an elastomeric core 16 between the two rigid plates. Each of the flat plates is covered with a porous coating 26 and from each of the flat plates extend a plurality of anchoring elements 28 capable of being introduced into the vertebra. The anchoring elements each include lumens 29 therethrough which allow communication of the interior thereof with the exterior. It would have been obvious to one of ordinary skill in the art at the time of the present invention to have provided lumens within the teeth the prosthesis of Büttner-Janz et al. so as to allow for communication of the interior of the teeth with the exterior thereby improving biocompatibility and/or ingrowth characteristics.

3. Claims 43 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Büttner-Janz et al. in view of Steffee as applied to claims 41 and 53 above, and further in view of

Art Unit: 3732

reasoning which follows. Büttner-Janz et al. and Steffee teach all of the limitations of the present invention except that the lumens within the teeth or anchoring elements are .5 mm in diameter. Applicant has not convincingly demonstrated the criticality of this particular dimension and it would therefore have been an obvious matter of design to one of ordinary skill in the art at the time of the present invention to have formed the lumens of whatever diameter was appropriate to the dimensions of the device as whole.

Allowable Subject Matter

1. Claims 42, 54 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
2. Claim 52 is allowed.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 3732

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Thurs. from 7:30 a.m. to 4:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding, should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Michael B. Priddy

Michael B. Priddy
03/08/2002

Jeffrey A. Smith
JEFFREY A. SMITH
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application.